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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,046	12/05/2003	Alexander M. Harmon	022956-0235	9312

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NUTTER MCCLENNEN & FISH LLP  
WORLD TRADE CENTER WEST  
155 SEAPORT BOULEVARD  
BOSTON, MA 02210-2604

EXAMINER
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STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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05/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,046	<b>Applicant(s)</b> HARMON ET AL.	
	<b>Examiner</b> Alvin J. Stewart	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-13, 20 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-13, 20 and 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                              |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/27/07</u> . | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/08/2007 has been entered.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 9-13, 20, and 23-28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In claim 1, lines 4 and 5, the applicant positively recites part of a human, i.e. "including an effective amount of viable cells that naturally occurs within the tissue slice...". Thus, claims 4 and 5 include a human part within the scope of the invention and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F. 2d 897, 164 USPQ 636 (CCPA 1970).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-13, 20 and 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 20 are indefinite because they use the phrase “effective amount”. For example, as disclosed in the MPEP 2172.05 (a), section III, the common phrase “an effective amount” may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA1975).

The phrase “an effective amount” has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954).

In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an “effective amount of a compound of claim 1” without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected. However, in light of the Applicant’s disclosure the claims are indefinite because they don’t provide guidelines to the intended utilities or how the uses could be effected.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 102***

Claims 1-3, 9, 10, 20 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kandel et al US Patent 6,077,989.

Kandel et al discloses a biocompatible tissue implant comprising a naturally occurring biocompatible tissue slice (see col. 3, lines 55-62; col. 11, lines 63-67; col. 12, lines 1-6; and Fig. 2) having a geometry, the tissue slice including an effective amount of viable cells (see col. 3, lines 52-67) and further being dimensioned so that the cells can migrate out of the tissue (see col. 12, lines 13-21) disclosing the tissue strip and the sutures.

Regarding claim 3, see col. 4, lines 62-67.

Regarding claim 9, see Fig. 2 disclosing a tapered shape and interpreted as a tissue tacks.

Claim 9 is a Markush claim, therefore, claim 10 has not been examined because the examiner only look for a tissue tack and not an adhesive.

Regarding claim 23, see col. 3, lines 39-50.

Regarding claim 24, see col. 11, lines 40-62.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kandel et al US Patent 6,077,989 in view of Lafrance et al US Patent 2003/0027332 A1.

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Kandel et al discloses the invention substantially as claimed. However, Kandel et al does not disclose a tissue slice having a thickness in the range of about 200 microns to about 500 microns.

Lafrance et al teaches an implant having a tissue slice with a thickness in the range of about 200 microns to about 500 microns (see paragraph 15) for the purpose of withstanding forces within the human body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Kandel et al reference with the thickness of the Lafrance et al reference in order to withstand forces within the human body.

Claims 11-13 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kandel et al US Patent 6,077,989 in view of Brauker et al US Patent 6,773,458 B1.

Kandel et al discloses the invention substantially as claimed. However, Kandel et al does not disclose at least one minced tissue fragment containing a plurality of viable cells.

Brauker et al teaches a tissue implant comprising at least one minced tissue fragment (with a size range of about 1 mm<sup>2</sup>) containing a plurality of viable cells for the purpose of increasing the biocompatibility of the implant (see col. 13, lines 51-59).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Kandel et al reference with the Brauker et al reference in order to contain a plurality of viable cells for the purpose of increasing the biocompatibility of the implant.

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***Response to Arguments***

Applicant's arguments with respect to claims 1-6, 9, 13, 20, and 23-28 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*A. Stewart*

**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
Art Unit 3738

May 15, 2007.